The applicant has amended claims 16, 21, 23, 28, 32, 36 and 47 to clarify them and to correct inadvertent errors therein.

The Examiner begins by rejecting claims 2, 6, 23, 27 and 47 under the first and second paragraphs of 35 U.S.C. 112 as not being based on an enabling disclosure in failing to set forth the subject matter which the applicant regards as his invention, and as not being complete because of omitting essential elements, and further, as not being complete because of omitting essential cooperative structural relationships between the elements therein. The Examiner contends that these claims fail to recite an adhesive engagement means and, in the instance of claim 47, further fail to affirmatively recite a resilient member which is mentioned only inferentially therein. The applicant has amended claim 47 above to affirmatively recite the presence of a resilient member therein, and so believes that this aspect of these rejections is overcome.

As to adhesive engagement means, the applicant does indeed describe in the specification of the present application a nasal dilator that is connected to a user's nose during use through that dilator adhering to the nasal outer wall tissues. However, the applicant does not see, nor does the Examiner point out, any statement in the specification in which the applicant takes the position that adhering this dilator to the outer wall tissues of a user's nose is the only manner of forming a sufficient mechanical connection to these wall tissues. Mechanical connection arrangements have highly predictable static and dynamic performances, and in situations of that sort the applicant is required to merely give a single example of a connection of a dilator to the outer wall tissues of the user's nose sufficient to necessitate those tissues mechanically following positions taken by that dilator under the resilient force generated therein. A sole example is clearly sufficient in these circumstances to describe and demonstrate the mechanical arrangement involved to one skilled in the art, and so sufficient to support claim wording reasonably related to such connections for mechanical purposes such as is used in the rejected claims.

Furthermore, the applicant specifically disclosed the language appearing in present claims 2 and 23 involving the dilator engaging the outer wall tissues, or the surfaces thereof, as can be seen in originally filed claim 1 that forms part of the disclosure, this claim stating the engagement

of the outer wall tissues by the dilator without reference to an adhesive. Thus, these claims are supported both by the literal disclosure in the application, and by the usual breadth given to claims in predictable arts after disclosure of a workable structure or method. Hence, the applicant respectfully submits that the rejected claims meet the requirement of having suitable support in the disclosure provided in the present application.

The Examiner then rejects claims 2 through 7, 16, 21, and 23 through 48 under 35 U.S.C. 112 as being indefinite in several instances. The Examiner correctly points out that there is a word missing in the last two lines of claim 23 which has been corrected by applicant in the above amendment.

The Examiner finds a lack of clarity in the last element of claim 16, and insufficient antecedent bases for two phrases therein. In addition, the Examiner believes the word --comprising-- should have been used in place of the word "having" in the first element of the claim, and that there is a confusion in lines 4 and probably 5 of that element. Again, the applicant believes that these situations have either been corrected or eliminated by the above amendment. In addition, some similar changes have been made in other pending claims at corresponding locations therein for purposes of also clarifying them.

The Examiner then goes on to reject claims 21, 32, 33 and 36 under 35 U.S.C. 102(b) as being anticipated by Spanish Utility Model 289561. The basis for such a rejection is stated by the Examiner to be that all of the elements in the rejected claims appear in the disclosure of this document upon which the Examiner has relied for the rejection. However, claim 21 clearly requires a flexible strip of deformable material to be positioned between the resilient member and those outer wall tissues that are engaged during use. There is no such showing in the Spanish reference.

As to claim 32, there is a requirement at the end of the first element of that claim that the resilient member be in contact with an adhesive at a surface thereof that is oriented as are the end surfaces of the truss, these end surfaces described as being capable of engaging the user's nose. Thus, a spring surface with adhesive thereon facing the user's nose during use must be in the dilator to meet claim 32. However, in accord with the Examiner's observation at a later point in the Action,

the Spanish reference describes an elastic spring strip 1 that is stuck to a "body" 2 by adhesive on that body, and then describes that body adhesive also being used to stick the resulting combination of strip and body to the user's nose as a dilator. There is no indication in the reference of a separate adhesive being provided on or applied to the elastic spring strip. Hence, claim 32 cannot be met by the Spanish reference dilator, and claim 33, in depending on claim 32, can not be anticipated if claim 32 is not anticipated.

Claim 36 also sets forth a dilator not found in the Spanish reference. A resilient member is required in that claim to be in contact with an adhesive at a surface thereof that is oriented as the end surfaces of the truss which, again, are recited as surfaces capable of engaging the outer wall tissues of a user's nose. Thus, here too, that resilient member surface contacting adhesive is required to face the user's nose during use. In addition, this surface is further required to be adhered to a flexible strip of material. Clearly, no surfaces of the spring in the Spanish reference facing the user's nose are adhered to any flexible strip of material, and thus this claim also cannot be anticipated by the disclosure in that reference.

The Examiner finishes by rejecting claims 2, 4 through 7, 16, 23 and 27 under 35 U.S.C. 103 as being obvious in the face of the Spanish reference. The Examiner first concludes that (a) the positioning of the spring in the truss of a nasal dilator against the outer surface of the user's nose between any remaining truss structure and that nose, versus (b) the alternative positioning of that remaining truss structure against the user's nose between the spring and that nose, is an irrelevant difference, and so rejects claim 2 over that reference. This conclusion is reached on the basis that the elastic or spring strip of the Spanish reference dilator generates the same forces in that dilator arrangement as the spring bands generate in the dilator arrangement of the present invention. However, this basis is offered without support, and generating adequate support would be difficult because the same forces are not generated in these two alternative arrangements either in the spring strips or bands involved or in the nasal tissues affected by them during use.

Certainly, a spring band or strip that is bent about the bridge of a user's nose so as to have its ends reach the opposite sides of that nose will, in either arrangement, tend to return to its

initial unbent state. This tendency, due to the bending resilience of the spring band or strip, creates forces at and near its ends, and at locations therebetween, that are directed outwardly from those sides. Nevertheless, the applicant cannot accept the Examiner's assertion that the same forces are generated during use in the spring strip that are generated in the bands provided in these two alternative arrangements. The differences in forces between those present in the spring strip used in the Spanish reference dilator arrangement and those in the bands used in the present invention dilator arrangement occur because of the different loading effects on them in those two arrangements due to the differing natures of the remaining portions of the truss in each.

More importantly, even if the spring strip or bands in both dilator arrangements did have the same forces present therein, the forces experienced at the outer wall tissues of noses on which those dilators are used will clearly not be the same. This follows because responses in remaining portions of the trusses to the spring forces exerted thereon will lead to differing deformations of these remaining portions as they are adhered to such tissues in the users' noses. Such differing deformations in these remaining truss portions lead to different resulting forces on those nasal outer wall tissues.

First, as to forces occurring in dilator spring strips or bands, the Spanish reference dilator during use has "body" 2 thereof, in reacting to the outward forces generated in elastic spring strip 1 by the bending of it, apply a reactive force to that strip. Such a reactive force differs from the comparable reactive force that flexible material strip 18 will apply to resilient bands 30a and 30b of the present invention in reacting to the forces generated by those bands after the bending thereof during use. In the Spanish reference dilator, body 2 will be adhered to the nasal tissues of a user by the portions thereof against the user's skin which are the portions thereof located outside the perimeter of spring strip 1. Therefore, body 2 will transmit the pulling forces of that spring strip primarily in the portions thereof extending beyond the edges of the spring strip, and especially so in the absence of any adhesive thereon . Consequently, the reactive forces of body 2 on spring strip 1 will be concentrated primarily on and near the ends of that strip where the largest spring forces tend

to occur because of body 2 primarily there limits the return of the spring from its larger deflections with respect to its unbent state.

These reactive forces in body 2 at spring 1 will, by extension, lead to countering reactive forces in the nose tissue at the ends of body 2, and these latter forces will be primarily concentrated on the those portions of the nasal outer wall tissues to which body 2 is adhered. Such tissue portions are those portions relatively near the cheeks of the user past the ends of the dilator, those portions well supported by cartilage located near bone in the user's nose toward the upper part of the nose past the upper edges of the dilator, and those portions near the nostril openings. That is, the reactive forces occur in all those tissue portions which are located past the end edges of spring strip 1 when the dilator is mounted on a user's nose in typical fashion.

On the other hand, resilient bands 30a and 30b in the dilator of the present invention will exert an outward force on the portions of flexible material strip 18 directly thereunder, i.e. those portions of that strip to which these bands are directly attached. In reaction, flexible material strip 18 will pull inwardly on resilient bands 30a and 30b where they are adhered thereto all along the undersides of those bands at locations at which the band spring force is directed outwardly. In a countering reaction, flexible material strip 18 will by extension pull outwardly on those portions of the outer nasal wall tissues of the user's nose under resilient bands 30a and 30b, and pull outwardly, and to some extent laterally, on adjacent region portions of tissue just outside the periphery of those bands. These adjacent region portions extend from those band edges all the way to just outside the periphery of flexible material strip 18 because of the adhesive thereon. Such differences in where the reactive forces occur on spring strip 1 of the Spanish reference dilator, and where reactive forces occur on bands 30a and 30b in the dilator of the present invention, lead to the reactive loading on spring strip 1 being significantly different than the reactive loading occurring on resilient bands 30a and 30b.

This different reactive loading on spring strip 1, as compared to the reactive loading on resilient bands 30a and 30b, leads to different stresses occurring in spring strip 1 as compared to the stresses that occur in resilient bands 30a and 30b. These differing stresses due to differing

external loadings yield different resulting geometries for spring strip 1 versus bands 30a and 30b after installation, and so to different spatial force distributions therealong because of the forces generated by each being strongly dependent on the degree and nature of the bending it undergoes. Therefore, the effective degree of return to the initial states that spring strip 1 or bands 30a and 30b were in prior to the bending thereof around the user's nose differs for each, i.e. they are not the same as asserted by the Examiner.

In addition, the forces and distribution of forces across the whole of the dilator generated by the Spanish reference dilator versus what is generated by the dilator of the present invention, after installation on a user's nose, must clearly differ on another ground. The use of a single, centered, relatively wide spring strip in the Spanish reference dilator versus the use of a spaced apart pair of relatively narrow bands in the dilator of the present invention will further add to the loading differences experienced by each.

Secondly, as to forces occurring on the outer nasal wall tissues of noses of dilator users, those forces imposed on such tissues by the Spanish reference dilator will differ significantly from those imposed on such tissues by the dilator of the present invention because of the differing truss structure deformations as indicated above. As a result, the comfort experienced by users during use of these alternative dilators will also differ. As an example, a common occurrence during dilator use is the wrinkling of the user's nose, i.e. a furrowing of the nasal outer wall tissues over the cartilage underneath. Such wrinkling is either due to internal forces generated by voluntary muscular movement of that nose or by involuntary muscular movement, such as from sneezing, or otherwise due to external forces such as the user's nose being against a pillow or the like, or some combination thereof. Accordingly, there is a resulting urging for the dilator and portions of the outer nasal wall tissues involved to move with respect to one another.

In such wrinkling situations with the Spanish reference dilator, substantial shear forces occur between the outer nasal wall tissues and body 2 therein because of body 2 being adhered to tissue portions at the peripheral edges of spring strip 1, and then extending over those edges to be further adhered to the outer surface of that strip. This adherence arrangement for body 2 leaves these

tissue edge portions unable to significantly furrow insofar as being free enough to move underneath spring strip 1 except to the extent that these tissues can pull the edge portions of body 2 underneath the edges of spring strip 1 with them. The rigidity of spring strip 1 in its lateral direction across its width will limit any such motion of the outer nasal wall edge tissues adhered to body 2 to only very small displacements thereof. As a result, large shear forces will occur during attempted nose wrinklings between the portions of body 2 at the lateral edges of spring strip1 and the edge portions of the outer nasal wall tissues to which these body 2 portions are adhered because of the limiting of any such tissue displacements, in response to the wrinkling forces, by body 2 and strip 1. Such large shear forces imposed on these edge tissues will lead to an uncomfortable result for the user.

On the other hand, flexible strip of material 18 in the dilator of the present invention can deform to a significantly greater degree while making relatively smaller angles with the tissue surfaces because of not being adhered to the top of bands 30a and 30b, but instead being adhered to the bottom thereof. As a result, the tissues at the edges of these bands can be displaced under them to the extent they would be displaced absent the bands in response to the wrinkling forces because of the flexibility or deformability of strip 18, and because their maximum distances from the top surfaces of the bands are not fixed by that strip. This situation allows the outer nasal wall tissues in those locations to move beneath these resilient bands without the occurrence of large increases in shear forces at those locations anywhere over a significant range of such displacements. Such a result affords the user a far more comfortable experience in those situations in which the outer nasal wall tissues are voluntarily or involuntarily forced to move unevenly along the supporting bone and nasal cartilage therebelow, i.e. during tissue wrinkling or furrowing.

Also abundantly clear in such situations, in connection with the rejection of claims 23, 34 and 37, is that the use of two narrow resilient bands, having a relatively large easily deformable expanse of flexible material strip 18 therebetween, will provide far more comfort than will the use of a single wide spring strip during such dilator motions. Spring strip 1 of the Spanish reference dilator, of course, serves as a resilient spring for bendings thereof across the bridge of a user's nose. However, because of its relatively narrow width and, more importantly because of

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having already been bent across the bridge of the nose, spring strip 1 behaves much as a laterally rigid plate with respect to any attempted additional bendings thereof in a perpendicular direction along the bridge of the nose. The bending of spring strip 1 over the bridge to conform about a user's nose for subsequent use effectively introduces a "stiffening rib" along the width of that strip at and near the bridge of the user's nose. Thus, spring strip1, insofar as its width near its center, is a laterally rigid plate even though flexible for bendings over the bridge of the user's nose. This portion of spring strip 1 is fixedly positioned over an expanse of the Spanish reference dilator that is located at approximately the same position therein as is the deformable expanse between the bands in the dilator of the present invention. Furthermore, as described above, the Spanish reference dilator spring strip, behaving as a laterally rigid plate, has the tissues located adjacent to its edges adhesively pinned in position relative to those edges resulting in substantial shear stresses in those edge tissues as they try, unsuccessfully, to follow the remaining nasal wall tissues during a wrinkling of the nose.

In comparison, again as described above, the nasal outer wall tissue portions at the edges of the bands in the dilator of the present invention can move under the bands during such nose wrinklings due to deformation of strip 18 to relieve such stresses that would otherwise occur. However, not only is that relief provided by flexible strip 18 to such tissue edge portions, but also the edges of these two bands can move both toward and away from one another in response to nose wrinklings to reduce the need for edge tissues to move thereunder during wrinklings. This relative movement of band edges is available because of the large, easily deformable expanse of flexible material strip 18 between the bands, and so its presence provides further stress relief to the tissue portions located adjacent to the band edges.

This difference in shear force results in the face of lateral movements of the outer nasal wall tissues along the supporting bone and nasal cartilage therebelow in wrinklings would be true between the dilator of the Spanish reference and the dilator of the present invention even if the nose tissues initially were absolutely flat underneath those dilators after installation thereof. However, the outer nasal wall tissues of a user will typically have undulations present therein to a greater or lesser degree, not only as a result of any wrinkling of the user's nose, as described above,

but also because the user's nose has an outer surface which is generally not flat in its natural state. Instead, nose outer surfaces typically have geometric undulations therein. Flexible strip of material 18 can deform to extend into pockets and valleys formed by such natural state undulations so as to maintain adherence to the outer nasal wall tissues all across that surface even with such undulations therein.

On the other hand, the rigid, relatively large surface area of spring strip 1 of the Spanish reference dilator that is positioned against the undulating nose tissue surface means that at least the deeper portions of the corresponding pockets and valleys are never against that spring strip. As a result, separated gaps are left at locations distributed across the spring strip surface where there is no contact with the outer nasal wall tissues. Further, spring strip 1 of the Spanish reference dilator is a solid offering little or no porosity, and is adhered tightly to the nose by body 2 at the ends thereof and also in the center where bent over the bridge. As a result, moisture accumulates under spring strip 1 both because of this area of nonporous spring surface being relatively large, and because that surface is maintained tightly against the skin thereby eliminating lateral paths to the edges of the spring for the trapped moisture. Such moisture accumulates in these gaps where it can further move over various gap surfaces especially as the user moves his nose thereby causing irritation and itching.

Furthermore, flexible strip of material 18 of the present invention can be porous, or "breathable", so as to allow air and moisture to pass laterally therethrough under bands 30a and 30b. This substantially aids in preventing excessive moisture accumulation at the surface of the outer wall tissues of the user's nose under these bands which could otherwise lead to skin maceration and so irritation.

This situation points up the value of the present invention in allowing for a wider choice of materials to be placed against the outer wall tissues of the user's nose to ease the finding of a material more compatible with those tissues than will be the material of a resilient member. The choice of material for the Spanish reference dilator spring strip is limited to a much narrower range of materials because of the need to be capable of supplying a sufficient resilient spring force. In the present invention, a material compatible with the skin of a user's nose, and capable of providing a

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"breathable" interface with those tissues, can be chosen for direct use against such tissues without regard to its resilient force capabilities. Instead, the material for used for the resilient band is separated from these tissues by this flexible material strip.

Further, the use of two resilient bands separated by a relatively large expanse of a material therebetween that can be both deformable and "breathable" provides a substantial increase in the ability of moisture to escape from underneath the dilator, and in the ability of air to pass therethrough to reach the outer nasal wall tissues covered thereby. This capability reduces the risk of damage to such skin due to maceration of those tissues. As with edge tissue stresses described above, there is no recognition of the benefits of multiple resilient bands, or springs, in nasal dilators in the Spanish reference, and so claim 23 is clearly allowable thereover (and apparently also claims 34 and 37 though not specifically rejected). Similarly, there is no recognition therein of the substantial improvement in comfort due to providing flexible material strip 18 beneath these bands to be between them and the user's nose during use, thus showing claim 2 and the claims dependent thereon to also be clearly allowable.

Claim 16 is next rejected by the Examiner because of the recitation therein of a truss with a plastic material flexible strip serving to merely substitute one known elastic material for another on the basis of economics in view of the Spanish reference description of an elastic strip. However, claim 16 also recites that this strip must also be positioned between the resilient band and the user's nose which has substantial advantages, as described above, and which is not shown in the Spanish reference. Thus, the applicant respectfully submits claim 16 is clearly allowable over the Spanish reference.

The Examiner, in thereafter rejecting claims 35 and 38, states that the Spanish reference dilator, in the embodiment formed by spring strip 1 being covered by body 2, has an inherent adhesive void. That is, as mentioned above, the Examiner observes that there is no adhesive on spring strip 1 to initially adhere that spring to the outer nasal wall tissues of the user's nose, and to thereafter aid in holding that spring against those tissues, and so finds that a void has been disclosed. However, this embodiment of the Spanish reference dilator, a dilator apparently formed

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by merely having adhesive tape placed over a bare plastic spring strip, is an essentially inoperative device.

Such an absence of adhesive on the relatively large area surface of spring strip 1, a surface area for such dilators in typical positions on users' noses that covers essentially that entire portion of the outer nasal wall tissues subject to being drawn in during inhalation, leads to little or no outward force being applied to most of those tissues. Rather, as described above, the entire force generated by spring strip 1 is essentially transferred through body 2 to those edge portions of the outer nasal wall tissues located at the periphery of spring 1, including through such portions of body 2 as are adhered to those edge tissues. Since spring strip 1 is not adhered to those tissues underneath it but only to those tissues adjacent to it through body 2, this spring has a resulting radius of curvature which is as great as allowed by body 2 so that the spring separates from those tissues primarily between the ends and the center thereof.

As a result, nearly all of the outward force of spring 1 is applied to portions of the outer nasal wall tissues which are little, or not at all, drawn inward during inhalation. This is because most of such outlying tissues are prevented from being drawn inward during inhalation by the support provided thereto by the bone in the cheeks and the nasal cartilage adjacent to bone in the upper part of the nose. The remaining outlying tissues at the periphery of spring 1, near where the nostrils open to the surrounding atmosphere, do not experience a sufficient pressure differential during inhalation to result in being significantly drawn inward. Applying outward forces to such peripheral tissue regions has the effect of rendering the Spanish reference nasal dilator embodiment based on adhesive tape over a bare plastic strip either useless or nearly so as to thereby provide little or no relief to a user.

In addition to the Spanish reference dilator being substantially inoperable because of its adhesive void, the applicant respectfully directs the Examiner's attention to the wording of claims 35 and 38. This wording requires that an adhesive void, or that a differing adhesion due to some adhesive void, occur only in a portion of the intermediate segment so as to leave the truss end surfaces fully adhered to the outer nasal wall tissues of the user's nose. Thus, these claims, in being

directed to a workable adhesive void arrangement, fully distinguish over the Spanish reference teaching. This teaching of no adhesive on spring strip 1 results in that void extending to very nearly the ends of the dilator disclosed in that reference to certainly involve its end surfaces in contrast the wording of these claims.

In view of the foregoing, the applicant respectfully requests the Examiner to reconsider her rejection of the claims as amended, and further requests these claims now be allowed as amended.

Any inquiries regarding this application should be directed to Theodore F. Neils at (612) 339-1863.

The Commissioner is authorized to charge any additional fees associated with this paper or credit any overpayment to Deposit Account No. 11-0982.

Respectfully submitted,

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TFN:nab
March 26, 1999